IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA
CENTRAL DIVISION

TERRENCE A. SMITH, Plaintiff, vs. SORIN GROUP DEUTSCHLAND GMBH and SORIN GROUP USA, INC., Defendants.	Case No. C17-3058 LTS **COMPLAINT AND JURY DEMAND**

COMES NOW Plaintiff, Terrence A. Smith, by and through his undersigned counsel, and alleges as follows:

PARTIES TO THIS ACTION

1. Plaintiff Terrence A. Smith is a resident and citizen of Carroll County, State of Iowa. On February 23, 2015, Plaintiff underwent open-chest cardiovascular surgery at the Mayo Clinic in Rochester, Minnesota. During the procedure, the Stöckert 3T ("3T System") heater-cooler system was used, exposing him to Mycobacterium avium and Mycobacterium Chimaera infection.

2. Defendant Sorin Group Deutschland Gmbh ("Sorin") is a foreign corporation headquartered in Munich, Germany. Defendant Sorin Group USA, Inc. ("Sorin USA") has a principal place of business in Arvada, Colorado. Defendants Sorin and Sorin USA are wholly-owned subsidiaries of LivaNova PLC.

3. Defendants designed, manufactured, marketed and sold the 3T System used in Plaintiff's surgery.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) because complete diversity exists between the parties and the amount in controversy exceeds $75,000.00. Personal jurisdiction exists over the Defendants in the U.S. due to the general and specific contacts they maintain in the U.S., and specifically in the State of Iowa.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendants do substantial business within this jurisdiction and are subject to personal jurisdiction in the District of Iowa.

FACTUAL ALLEGATIONS

6. The Defendants design, manufacture, market, and sell thermal regulator devices to be used on patients in operating rooms, including the 3T System.

7. Prior to February 23, 2015, the Defendants designed, manufactured, sold, and/or delivered for introduction into interstate commerce, the 3T System.

8. The 3T System is intended to provide temperature-controlled water to heat exchanger devices to warm or cool a patient during a surgical procedure such as the Plaintiff's in this case. The 3T System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") regulation.

9. On October 13, 2016 an official health advisory from the Centers for Disease Control and Prevention ("CDC") stated that hospitals are advised to notify patients who underwent open surgery involving the 3T System that the device was potentially contaminated with bacteria, putting patients at risk for a life threatening infection. The bacterium at issue, Mycobacterium Chimaera, is a subspecies of nontuberculous mycobacterium ("NTM").

10. Within days of the CDC advisory, the Mayo Clinic ("Mayo") assembled a crisis management team and identified more than 17,000 patients (including Plaintiff) who underwent cardiac surgery at 1 of their 4 sites (Mayo Clinic in Rochester, Minnesota, Phoenix, Arizona, and Jacksonville, Florida, and Mayo Clinic Health System-Eau Claire Hospital in Eau Claire, Wisconsin) within the last 5 years, and sent letters to each of the patients advising them of the recently discovered risk of infection.

11. At the time Mayo sent the letters to the 17,000 patients who received surgery using the 3T Device, they had only confirmed one patient who had been diagnosed with the infection caused by the bacteria. That one patient was Plaintiff Smith.

12. On July 15, 2015, the FDA issued a Class II Recall of the 3T System due to the potential colonization of organisms, including Mycobacteria, in the 3T System devices, if proper disinfection and maintenance is not performed per instructions for use.

13. The recall instructed all affected customers to follow new Instructions for Use, which were outlined in a June 15, 2015 Field Safety Notice Letter for EU English-speaking countries, followed up by a similar letter to users in the United States on August 6, 2015, both issued by i.V. Christian Peis, the Director of Quality Assurance for Defendants.

14. Defendants indicated that they were providing the Field Safety Notice Letters for the following reasons: (A) To remind affected users of the importance of following the company's disinfection and maintenance procedures; (B) To inform affected users that there is a possibility that bacteria can become aerosolized when the heater-cooler device is operated and serve as a source for contaminations; and (C) To

provide affected users with updated instructions for use regarding disinfection and maintenance procedures.

15. Defendants knew or should have known that the design and/or manufacturing defects in its 3T System made it susceptible to bacterial colonization, specifically Mycobacteria, despite any cleaning and disinfection procedures utilized.

16. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Defendants' Germany and Colorado facilities revealed that the 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packaging, storage, or installation [were] not in conformity with current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations, Part 820."

17. Contrary to the Defendants' representations and marketing to the FDA, medical community, and to the patients themselves, Defendants' 3T System has high injury and complication rates, fails to perform as intended, requires patients to undergo additional operations, and has caused severe and irreversible injuries, conditions, and damages to a significant number of patients, including Plaintiff Smith.

18. Defendants knew, and continue to know, that its disclosures to the FDA, the public, and Plaintiff were, and are, incomplete and misleading and that the 3T System was and is causing numerous patients severe injuries and complications. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, the medical community, healthcare providers, and patients. As a result, the Defendants actively and intentionally misled the FDA and the public, including the medical community,

healthcare providers, and patients, into believing that the 3T System was safe and effective, leading to the use of Defendants' system during surgical procedures, such as the one undertaken by Plaintiff, as more fully described herein.

19. In violation of Federal rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the 3T System.

20. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use have existed at all times relevant herein.

21. The Defendant's 3T System was at all times relevant herein, utilized in a manner foreseeable to the Defendants.

22. The 3T System used during Plaintiff's surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants, and in the condition directed and expected by the Defendants.

23. The injuries, conditions, and complications Plaintiff suffered due to the 3T System include, but are not limited to, excruciating pain, weakness, excessive additional and debilitating medical conditions and treatment, suffering, loss of enjoyment of life, and permanent injury.

24. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the 3T System, it continued to manufacture, market, provide inadequate instructions for use, and sell the 3T System, and also failed to adequately warn, label, instruct, and disseminate information with regard to the Defendants' 3T System both prior to and after the marketing and sale of the System.

FACTS SPECIFIC TO THIS CASE

25. Defendants' 3T System was used during Plaintiff's surgery performed at Mayo Clinic on February 23, 2015, wherein the Plaintiff's surgeon, Dr. Lyle D. Joyce, used the device to assist in the cooling and re-warming of Plaintiff's blood.

26. Plaintiff's surgery on February 23, 2015 included implantation of Left Ventricular Assist Device, HeartMate II ("LVAD") as destination therapy with aortic valve replacement, and coronary bypass grafting times two. Following post-surgical care, Plaintiff was discharged from the Mayo Clinic on April 27, 2015.

27. Plaintiff returned to Mayo Clinic on March 10, 2016 for one year routine clinic evaluation by Dr. Lyle D. Joyce, but because of issues with wound healing and after detecting tunneling from the wound site and possible LVAD driveline involvement, Dr. Joyce re-admitted Plaintiff to Mayo Clinic and performed a debridement procedure on March 11, 2016, during which LVAD driveline, sternal wound, and blood cultures were all obtained.

28. Cultures taken during the March 11, 2016 procedure were positive for Mycobacterium Avium complex, and upon Plaintiff's discharge on March 25, 2016, his primary diagnosis was "Mycobacterium avium sternal/epigastric surgical site infection-involving proximal portion of LVAD driveline."

29. Plaintiff was again admitted to the Mayo Clinic on August 12, 2016 and underwent three more debridement procedures on August 12, 13 and 15. He was discharged on August 18, 2016 with the primary diagnosis of "Mycobacterium avium and Mycobacterium Chimaera sternal/epigastric surgical site infection."

30. Plaintiff was again admitted to the Mayo Clinic on September 22, 2016 and underwent surgical debridements on September 23, 26, 27, 30, October 3, and 5. He was

discharged on October 11, 2016 with the primary diagnosis of "LVAD driveline exposure at sternum in context of Mycobacterium avium and Mycobacterium Chimaera sternal/epigastric surgical site infection."

31. During Plaintiff's Mayo Clinic hospitalization of September 22, 2016 to October 11, 2016, he was informed by Mayo Clinic medical personnel that he had been exposed to Mycobacterium avium and Mycobacterium Chimaera during his initial surgery on February 23, 2015, and that the source of the bacteria was the 3T System that was used during his surgical procedure.

32. Plaintiff has been prescribed powerful antibiotics to treat his infection and his treatment by physicians continues and is ongoing.

TOLLING OF THE STATUTE OF LIMITATIONS

33. Under Iowa law, the "discovery rule" tolls the statute of limitations when a plaintiff, due to facts or circumstances not within his control, is unable to discover his injury and its cause within the prescribed time period.

34. Under the "discovery rule," the statute of limitations begins to run when a plaintiff knows, or in the exercise of reasonable diligence should have known, that he or she has been injured, and that his or her injury was caused by the conduct of another.

35. Prior to the Mayo Clinic informing Plaintiff that he had been exposed to Mycobacterium avium and Mycobacterium Chimaera during his February 23, 2015 surgery, and that the source of the bacteria was the 3T System, Plaintiff was wholly unaware of both his exposure to the bacteria and that his exposure was caused by a defective medical device.

36. Any applicable statute of limitations has been tolled by Plaintiff's lack of knowledge of the facts alleged herein, prior to October of 2015.

COUNT I
Negligence – Design Defect

37. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

38. The 3T System is a product within the meaning of Iowa products liability law.

39. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

40. Under Iowa products liability law, Defendants owed Plaintiff a duty to exercise reasonable care in designing and testing the 3T System.

41. Defendants designed the 3T System for the purpose of heating and cooling patient blood during major open-chest cardiovascular surgeries that require a heart/lung bypass machine.

42. At all times material herein, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

43. A patient or consumer using the 3T System would reasonably expect the device to be free of significant defects.

44. The 3T System, as designed by the Defendants, colonizes bacteria, including Mycobacterium Chimaera.

45. The 3T System, as designed by the Defendants, directly transmits bacteria, including Mycobacterium Chimaera, to patients during invasive surgery.

46. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T System.

47. Reasonable alternative designs existed for the 3T System which would have eliminated or reduced the risk of bacterial colonization and/or transmission of such bacteria to patients undergoing invasive surgical procedures.

48. Reasonable and feasible alternative designs include, but are not limited to, measures to direct airflow away from the surgical field (i.e. a housing unit for the exhaust vent), reducing the force at which air is vented from the System to a rate of less than 1000 cubic feet per minute, water reservoir isolation by using closed loop fluid management, an open water design to prevent inaccessible airspace, removable lids and parts for easy disinfection, disposable tank liners to prevent biofilm formation, and internal pasteurization or UV features to kill bacteria.

49. The failure to use feasible, reasonable alternative designs that eliminate bacterial colonization and the aerosolization of bacteria into the ambient air of operating rooms renders the 3T System unreasonably unsafe.

50. Defendants knew or should have known as early as 2002 that NTM, or other harmful bacteria, could colonize within the 3T System and be spread to patients during surgery through the exhaust vent.

51. Plaintiff's injuries were caused by Defendants' conduct as follows:

a) Failing to conduct adequate safety and efficacy testing before placing the 3T System in the stream of commerce;

b) Failing to timely establish procedures for reviewing the design of the 3T System after receiving information that patients were developing bacterial infections as a result of surgeries using the 3T System;

c) Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the 3T System before their implementation as required under 21 CFR 820.30(i); and

d) Failing to design or redesign the 3T System to eliminate or mitigate bacterial colonization and/or transmission of such bacteria.

52. Plaintiff was proximately harmed by the design defects in the 3T System as described above.

COUNT II
Strict Liability – Manufacturing Defect

53. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

54. The 3T System is a product within the meaning of Iowa products liability law.

55. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

56. Defendants manufactured the 3T System for the purpose of heating and cooling patient blood during major open-chest cardiovascular surgeries that require a heart/lung bypass machine.

57. At all times material herein, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

58. A reasonable patient or consumer of the 3T System would expect the device to be free of significant defects.

59. The 3T System, as manufactured by the Defendants, colonizes bacteria, including Mycobacterium Chimaera, and directly transmits such bacteria to patients during invasive surgery.

60. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T System.

61. Plaintiff's injuries were caused by Defendants' conduct as follows:

a) Failing to timely establish procedures or practices to prevent the 3T System from being contaminated with NTM on the production line or elsewhere at Defendants' production facilities;

b) Manufacturing and selling the 3T System with NTM contamination that occurred on the production line or elsewhere at Defendants' production facilities; and

c) Failing to ensure proper workmanship, materials and labeling for the 3T System.

62. Plaintiff was proximately harmed by the manufacturing defects in the 3T System as described above.

COUNT III
Negligence – Warnings Defects

63. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

64. The 3T System is a product within the meaning of Iowa products liability law.

65. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

66. Defendants owed Plaintiff a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the 3T System.

67. Defendants marketed, advertised and promoted the 3T System for the purpose of heating and cooling patient blood during major open-chest cardiovascular surgeries that require a heart/lung bypass machine.

68. At all times material herein, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

69. A reasonable patient or consumer of the 3T System would expect that the device be free of significant defects.

70. The 3T System colonizes bacteria, including Mycobacterium Chimaera, and directly transmits such bacteria to patients during invasive surgery.

71. Defendants knew or should have known as early as 2002 that NTM, or other harmful bacteria, could colonize within the 3T System and be spread to patients during surgery through the exhaust vent.

72. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon the patients using the 3T System.

73. Plaintiff's injuries were caused by Defendants' conduct as follows:

a) Failing to provide proper cleaning and disinfection procedures for the 3T System;

b) Failing to conduct proper validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T System;

c) Failing to warn patients like Plaintiff Terrence Smith and/or purchasers of the 3T System that the system colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms;

d) Failing to timely notify known purchasers of the 3T System that patients could be exposed to NTM;

e) Failing to alert hospitals and patients to promptly test for NTM infection when patients present with fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue after surgery using the 3T System; and

f) Failing to timely notify known purchasers of the 3T System to relocate the device from the operating room during surgery to prevent patient transmission of NTM.

74. Plaintiff was proximately harmed by the warnings defects in the 3T System as described above.

Damages

75. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

76. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff has sustained damages including, but not limited to, the following:

a) Medical expenses – past, present, and future;

b) Pain and suffering – past, present, and future;

c) Loss of full mind and body – past, present, and future; and

d) Permanent injury and impairment.

Punitive Damages

77. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

78. The acts, omissions, and violations of the Defendants as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiff is entitled to an award of punitive damages.

PRAYER FOR RELIEF

Plaintiff, Terrence A. Smith, requests the Court to enter judgment against the Defendants as follows:

A. An award to Plaintiff of compensatory and punitive damages, costs and reasonable attorneys' fees, as permitted by law;

B. An award of pre-judgment and post-judgment interest, as provided by law;

C. Leave to amend this Complaint to conform to the evidence produced at trial; and

D. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues presented herein.

Dated: June 26, 2017

/s/ Michael G. Reilly
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